

SECTION E – 510(k) SUMMARY

Submitter's Name and Address:

Physio-Control, Inc.
11811 Willows Road Northeast
Redmond, WA 98052

JUL 29 2008

Contact Person:

Michelle Ackermann
Principal Regulatory Affairs Specialist

Date Summary Prepared:

October 31, 2007

Device:

LIFEPAK® 20e defibrillator/monitor

Classification:

Classification Name	Class
Low Energy DC-Defibrillator	II
Automatic External Defibrillator	III
Cardiac Monitor (Including Cardiotachometer & Rate Alarm)	II
Cardiac External Transcutaneous (Non-Invasive) Pacemaker	II
Electrocardiograph	II
Hydraulic, Pneumatic, or Photoelectric Plethysmographs	II
Oximeter	II

Substantial Equivalence:

The features and functions of the LIFEPAK 20e defibrillator/monitor are substantially equivalent to the previously cleared LIFEPAK 20 defibrillator/monitor (K063119, K033275, and K012274).

Description:

The LIFEPAK 20 defibrillator/monitor was created especially for hospitals and clinics for use on "crash carts" as well as for portable emergency response throughout a hospital. The LIFEPAK 20 defibrillator/monitor is equipped with AC power and a backup internal battery. Features of the LIFEPAK 20 defibrillator/monitor include manual and automated external defibrillation, noninvasive pacing, ECG monitoring (3-wire or 5-wire), pulse oximetry, and synchronized cardioversion.

The LIFEPAK 20 defibrillator/monitor has been modified with new battery technology. This modification includes a change in the chemistry of the internal battery from nickel-metal hydride to lithium ion, and the addition of a battery status indicator on the device display indicating the approximate amount of operating time available while using battery power.

The model name of devices with this new battery technology is the LIFEPAK 20e defibrillator/monitor.

Intended Use:

The LIFEPAK 20e defibrillator/monitor is intended for use in the hospital, physician's office, and clinic setting by personnel who are authorized by a physician/medical director. It is intended for use on a "crash cart" as well as for portable emergency response throughout a hospital.

Indications for Use:**Manual Defibrillation:**

Indications: Defibrillation is a recognized means of terminating certain fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of this energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal

supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

The biphasic defibrillation waveform used in this device has only been clinically tested on adults; it has not been tested on pediatric patients.

Contraindications: Defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA) such as idioventricular escape rhythms, and in the treatment of asystole.

Automated External Defibrillation:

Indications: The AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing normally before using the defibrillator to analyze the patient's ECG rhythm. In AED mode, the LIFEPAK 20e defibrillator/monitor is not intended for use on pediatric patients less than 8 years old.

Noninvasive Pacing

Indications: Noninvasive pacing is indicated for symptomatic bradycardia in patients with a pulse.

Contraindications: Noninvasive pacing is contraindicated for the treatment of ventricular fibrillation and asystole.

Pulse Oximetry

Indications: The pulse oximeter is indicated for use in any patient who is at risk of developing hypoxemia.

Technological characteristics of new and predicate device:

The main difference between the LIFEPAK 20e defibrillator/monitor and the predicate LIFEPAK 20 defibrillator/monitor is new technology for the internal backup battery and the addition of a battery status indicator on the device display. Features of the LIFEPAK 20e defibrillator/monitor such as the ECG analysis system, defibrillation waveform, and noninvasive pacing are the same as those of the predicate device.

Defibrillation technology and functionality of the LIFEPAK 20e defibrillator/monitor have not changed from the previously cleared LIFEPAK 20 device.

Summary of Design Controls:

This 510(k) includes a summary of design control activities and a declaration of conformity to design controls.

The information in this 510(k) notification demonstrates that the LIFEPAK 20e defibrillator/monitor is substantially equivalent to the predicate LIFEPAK 20 device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Physio-Control, Inc.
c/o Ms. Michelle Ackermann
11811 Willows Rd., N.E.
PO Box 97006
Redmond, WA 98052

Re: K073089

Trade/Device Name: LIFEPAK 20e Defibrillator/Monitor
Regulation Number: 21 CFR 850.5310
Regulation Name: Automated external defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: July 8, 2008
Received: July 10, 2008

Dear Ms. Ackermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

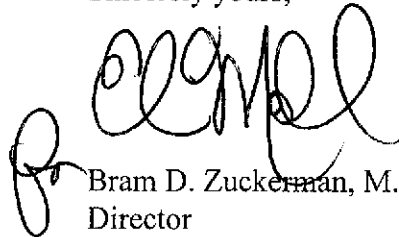
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807);

labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-3464. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', is written over the typed name.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION D – STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): not yet assigned

Device Name: LIFEPAK 20e defibrillator/monitor

Indications For Use:

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Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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